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To : Manuel Mendez **From :** tom merrill
Sent : 11/22/2005 at 12:20:14 AM **Pages :** 2 (including Cover)
Subject : 3rd office action - Active Mixing Patent 10/620,212

Hello Manuel:

I've tried my best to address your recent office communication.

Please take a look at my attempt to provide some clarification on patentability for Claims 14-31.

I'm eager to hear what you think. I will call you this week.

I appreciate your help Manuel.

Tom

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Commissioner for Patents
P.O. Box 1450
Alexandria , VA 22313-1450

RE: Application No. 10/620,212, Filing Date 7/15/2003, Office Action 11/16/05 Examiner Manuel Mendez

Hello Manuel,

My name is Tom Merrill and I'm the inventor on the above application. I tried connecting with you earlier today. I want to address your concerns accurately and completely. As you told me this summer your work load is very heavy and I want to go forward quickly – without a lot of additional burden for you or legal fees for me.

Before I argue patentability Manuel please let me make this introductory claim. There are no commercially available products that cool arterial blood flow. All existing products based on current patents cool venous blood – where vessels are substantially larger. My primary feature – dynamic surfaces – focuses on increasing heat transfer and reducing overall size to sustain adequate blood flow.

It's my understanding that patentability rejections are based on §102 and §103 so I'll break my arguments into two parts. They attempt to address your concerns on Claims 14-31 in general.

§102 – Novelty

- o Physical Feature: The feature of **heterogenous and compliant tubing** is not recited in any of references.
- o Operational Feature: The operation of **high frequency (1-20 Hz) surface pulsations for augmenting heat transfer** is a new use not cited in any of the references.
 - I agree that Taheri recites the use of pulsations to "prevent blood from clotting". However, it does not address the key arterial blood heat transfer challenge – effective heat exchange without constricting the blood flow area. As stated Taheri's patent, a simple homogenous compliant vessel will lead to a "constricted annular passageway" (Column 5, paragraph 1, Figures 1 and 2).

§103 – Nonobvious

- o These physical and operation features lead to new and unexpected results. Using the heterogenous compliant surfaces with high frequency pulsations leads to substantial increases in heat transfer performance (Figure 25 of this application is an example).
- o These features were recognized by the National Institute of Health as "highly innovative", rewarding me with a small business research grant to continue development (July 2005).
- o No reference or combination of references taught to combine these features to increase heat transfer and minimize blood flow restriction. None of the references discusses the potential negative impact of the heat transfer process on the blood flow process. The prior art features of uniformly expanding surfaces or corrugated surfaces do not address the unappreciated difficulty of transferring heat in a tiny 4 mm arterial vessel versus a large 25 mm venous vessel. The non-existence of arterial blood coolers supports this claim.

More specifically – Manuel you are correct to state that clarification is needed. Claim 43 includes an "alignment" claim (step 3 in this Method claim using "distal protection filter"). Yet, Claim 14 does disclose a feature that reduces catheter size: "a plurality of dynamic surface regions" disrupt boundary layers and increase heat exchange, allowing more heat exchange with smaller devices.

Sincerely,



Thomas L. Merrill

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